

JAN 13 2005

**X. PREMARKET NOTIFICATION SUMMARY**

**Submitted by:** Vitrolife Sweden AB  
Faktorvägen 13  
SE-434 37 Kungsbacka  
SWEDEN

**Contact Person:** Mr. Morgan Hugosson  
Vitrolife Sweden AB  
Faktorvägen 13  
SE-434 37 Kungsbacka  
SWEDEN

**Date Prepared:** November 1, 2004

**Trade Name:** ICSI™

**Common Name:** Assisted Reproduction Media

**Classification Name:** Reproductive Media and Supplements  
(21 C.F.R. § 884.6180)

**Predicate Device:** PVP-Polyvinylpyrrolidone device (K991343)

**Description of the Device:** Viscous sperm handling solution. Ready-to-use after equilibration at 15-25°C.

**Intended Use:** Medium for *In Vitro* Fertilization Procedures

**Indications for Use:** For the immobilization and isolation of sperm prior to intracytoplasmic sperm injection, ICSI.

**Technological Characteristics:** The technological characteristics of ICSI™ are essentially similar to those of the predicate device. None of these changes raise new questions of safety or effectiveness.



JAN 13 2005

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. Morgan Hugosson  
Regulatory Affairs Officer  
Vitrolife Sweden AB  
Faktorvägen 13  
SE-434 37 Kungsbacka  
SWEDEN

Re: K043116  
Trade/Device Name: ICSI™, Assisted  
Reproduction Media  
Regulation Number: 21 CFR 884.6180  
Regulation Name: Reproductive media  
and supplements  
Regulatory Class: II - -  
Product Code: 85 MQL  
Dated: November 1, 2004  
Received: November 26, 2004

Dear Mr. Hugosson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

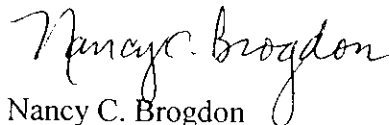
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

|                 |                                  |              |
|-----------------|----------------------------------|--------------|
| 21 CFR 876.xxxx | (Gastroenterology/Renal/Urology) | 240-276-0115 |
| 21 CFR 884.xxxx | (Obstetrics/Gynecology)          | 240-276-0115 |
| 21 CFR 892.xxxx | (Radiology)                      | 240-276-0120 |
| Other           |                                  | 240-276-0100 |

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



Nancy C. Brogdon  
Director, Division of Reproductive,  
Abdominal, and Radiological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): K043116

Device Name: ICSI™, Assisted Reproduction Media

Indications For Use: For the immobilization and isolation of sperm prior to intracytoplasmic sperm injection, ICSI

Prescription Use X  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

---

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy Brogdon  
(Division Sign-Off)  
Division of Reproductive, Abdominal,  
and Radiological Devices  
510(k) Number K043116

Page 1 of 1